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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/23/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,848

Applicant(s)

NIZARD ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: _____

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DETAILED ACTION

Claims 59-93 are pending. The Amendment filed 7/11/03, Paper No. 7, cancelled claims 26-58 and added claims 59-93.

Lack of Unity

Applicant has argues against the Lack of Unity requirement as if it were a US Restriction Requirement. It is respectfully pointed out that the criteria for establishing Lack of Unity and US Restriction Requirement are distinct. Thus, Applicant's arguments regarding burden and classification are moot.

In the second paragraph on page 4, Applicant states "a search for the power plant of claim 34, searching for the power plant of other independent claims would be minimally burdensome on the Examiner". The Examiner is not aware of what the Applicant is referring to in this statement, as the instant claims are directed toward cosmetic methods.

This lack of unity requirement, for reasons in the Office Action mailed 3/2/03, Paper No. 5, is made final.

It is respectfully pointed out newly added claims 59-93 correspond to elected claims 49-53 and 55-56 (Group IV).

Claim Objections

1) Claims 61 and 62 are duplicates of each other. The Examiner respectfully requests that one of these claims be cancelled or amended to distinguish them.

2) The term "intercellular" is spelled incorrectly in claim 60.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed toward a method of promoting and/or increasing the activity of a cosmetic agent acting directly in the cell or via intracellular second messengers, comprising the application of a cosmetic agent to the skin areas of a person in need thereof, of an effective amount of at least one substance promoting intercellular communication.

(2) The state of the prior art

The prior art is filled with cosmetic agents which promote intercellular communication, as most transdermally applied cosmetic agents are absorbed by the epidermis and other layers of skin and then transported across veins and arteries (blood vessel wall cells) in the blood stream or are absorbed by the epidermis which affects the dermis and other skin layers. For example see US 5,811,083 which teaches a topically applied composition that has its effects on the dermis, though the topical application occurs on the epidermis. However, the art is silent in regard to agents, whose activity is increased or promoted by being used in conjunction with active compounds that promote intercellular communication.

(3) The relative skill of those in the art

The relative skill of those in the art is high, as one of skill cannot predict how one compound will affect another compound or a physiological process when applied to the skin of a live person.

(4) The predictability or unpredictability of the art

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The unpredictability of the cosmetic art is very high, as it is impossible to know how two or more chemical compounds will behave in vivo and how their composition will affect one another and an in vivo physiological process.

(5) The breadth of the claims

The claims are very broad. The cosmetic agent can be anything and the substance promoting intercellular communication encompasses an incredible number of compounds because, as described above, most every topically applied cosmetic agent promotes intercellular communication.

(6) The amount of direction or guidance presented

The instant specification provides no guidance or direction as to what these cosmetic agents are or can be. The method is merely stated.

(7) The presence or absence of working examples

The instant specification provides no working examples of the method of claim 79.

(8) The quantity of experimentation necessary

Since it is impossible to predict the physiological effect of bringing two chemical compounds together, an incredible amount of experimentation would be required to determine what cosmetic agents and what substances can be combined to produced an increase in the activity/effect of the cosmetic agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-78 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "for obtaining an anti-ageing effect on said skin areas, for improving the firmness and elasticity of the skin, for delaying the appearance of wrinkles or for reducing their depth" in claim 59 (lines 3-6) is vague and indefinite, as it is confusing. Are not improving firmness and elasticity of the skin and delaying the appearance of wrinkles and reducing their depth, anti-ageing effects? Is Applicant claiming a range within a range?

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(ii) The phrase "said substance is presenting cosmetic composition" in claim 64 is vague and indefinite, as it is confusing. What does this phrase mean?

(iii) Claim 71 recites the limitation "the composition of claim 65" in line 1. There is insufficient antecedent basis for this limitation in the claim.

(iv) Claims 76 and 91 are vague and indefinite, as the scope of the claims is unascertainable. How can the conditions both comprise and consist essentially of? This is confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Pelle et al. (5,811,083).

Pelle et al. disclose in Col. 13, line 14-Col. 14, line 6, a method for treating or retarding lipid peroxidation-medicated skin aging in a patient which comprises topically administering to skin of a patient in need thereof a composition comprising a lipid peroxidation inhibiting amount of a tocopherol derivative. Col. 2, lines 36-37, teach the tocopherol derivative of Col. 13-14, as a novel tocopherol compound with enhanced antioxidant activity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briand (English Translation of FR 2,657,012) in view of Winget (5,767,095).

The instant invention is directed toward a method of skin care comprising applying to skin areas of a person in need thereof, an effective amount of at least one substance promoting intercellular communication for obtaining an anti-ageing effect, improving firmness and elasticity of skin, delaying the appearance of wrinkles, or reducing their depth, and a method of promoting and/or increasing the activity of a cosmetic agent acting directly in the cell or via intracellular second messengers, comprising the application of a cosmetic agent to the skin areas of a person in need thereof, of an effective amount of at least one substance promoting intercellular communication.

Briand teaches the use of microscopic algae extracts for the preparation of cosmetics, wherein the extracts have free radical reducing activity, wherein a decrease in free radical production is established in the art to reduce aging, see page 2. Skeletonema is specifically taught as a preferred extract, see page 3. The cosmetics are taught as compositions comprising algae extracts and additional cosmetic ingredients/agents for treating the skin, see page 12. External application is specifically taught, see page 12. Exemplified is a composition comprising 3% extract of Skeletonema. Briand does not teach the Skeletonema as a complete lipid extract, as water and an organic solvent art (ethanol and isopropanol) are taught as the extraction medium for Skeletonema.

Winget teaches anti-inflammatory compositions containing a purified microalgal lipid preparation for application to the skin. Skeletonema is specifically taught as a preferred algae. Such extracts are taught as imparting potent anti-inflammatory effects to the skin of a user. See Col. 1, line 19-Col. 2, line 55; Col. 10, lines 9-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a lipid extract of Skeletonema into the compositions of Briand or to teach the extracts of Briand as lipid extracts, as taught by Winget, because of the expectation of achieving a product that treats existing skin aging and protects against further skin aging by UV damage (effect of antiinflammatories).

Since a compound and its properties are inseparable, the Skeletonema of the combined references have the properties of promoting intercellular communication via gap junctions of keratinocytes, fibroblasts and skin preadipocytes and of promoting intercellular communication to promote the formation of connexin.

The claims are directed to a method of applying a composition comprising an extract of Skeletonema to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently treat aging or

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promote the activity of a cosmetic agent, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

The Examiner respectfully points out instant claims 63, 65-76, 80-91 are product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Regarding claims 76 and 91, it is respectfully pointed out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw



SREENI PADMANABHAN
PRIMARY EXAMINER

9/22/03